



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/910,120	07/18/2001	Dana Ault-Riche	25885-1751	1666

24961 7590 04/07/2005

HELLER EHRMAN WHITE & MCAULIFFE LLP  
4350 LA JOLLA VILLAGE DRIVE  
7TH FLOOR  
SAN DIEGO, CA 92122-1246

EXAMINER

TRAN, MY CHAU T

ART UNIT	PAPER NUMBER
----------	--------------

1639

DATE MAILED: 04/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/910,120	<b>Applicant(s)</b> AULT-RICHE ET AL.	
	<b>Examiner</b> MY-CHAU T. TRAN	<b>Art Unit</b> 1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 February 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-23,25-37,49-54,93-95 and 99 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-23,25-37,49-54,93-95 and 99 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 February 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. The examiner received a called from Mrs. Judy Sherman, who claimed to be the assistant to Mrs. Stephanie L. Seidman (attorney of record), stating that the Office Action mailed on 12/22/2004 was improper because the petition decision mailed 6/1/2004 also vacates the species election requirement. It is noted that the petition decision mailed 6/1/2004 was ambiguous regarding the species election requirement since there was two species election requirement (see office action mailed 10/02/2002 and 04/08/2003). The first species election requirement was withdrawn as noted in the Office Action mailed on 04/08/2003. Thus in order to further prosecution all species election requirements are withdrawn and the Office Action is a Non-final Office Action.

Applicant petition to rejoined Group III (Claims 49-54) with Group I (Claims 1-37, 93-95, and 99) was granted and the Office action mailed 2/25/2004 is vacated as indicated in the petition decision mailed 6/1/2004.

Furthermore, Mrs. Judy Sherman also requested the reconsideration in entering the amendment filed on 2/12/2004. This amendment (preliminary) filed on 2/12/2004 was not entered because it would unduly interfere with the preparation of the Office action, which was mailed on 02/25/2004. However in order to further prosecution, this amendment is now entered.

### ***Status of Claims***

2. Applicant's amendment filed 2/12/2004 is acknowledged and entered. Claim 24 has been canceled. Claims 1, 4, 8, 9, 11-14, 16, 20, 23, 25-35, 49, 50, 53, and 93-95 have been amended.

Art Unit: 1639

3. Claims 38-48, 55-92, and 96-98 were canceled and Claim 99 was added by the amendment filed on 12/27/2002.

4. Claims 1-23, 25-37, 49-54, 93-95, and 99 are pending.

***Priority***

5. This application claims benefit to a provisional application under 35 U.S.C 119(e). The provisional application is 60/219,183 filed 07/19/2000.

***Information Disclosure Statement***

6. The information disclosure statement(s) (IDS) submitted by applicant filed on 8/12/02; 10/9/02, 7/2/03, 6/18/2004, and 10/5/2004 are acknowledged and considered as noted on PTO-1449 forms. These PTO-1449 forms were mailed to applicant on 12/22/2004.

7. Claims 1-23, 25-37, 49-54, 93-95, and 99 are treated on the merit in this Office Action.

***Claim Rejections - 35 USC § 112***

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 1-23, 25-37, 49-54, 93-95, and 99 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Art Unit: 1639

a) Claim 1 recites the limitation of "set of capture agents" in line 23. There is insufficient antecedent basis for this limitation in the claim 1 since the claim 1 first recites the limitation of "*a collection of capture agents*". The limitation of "set of capture agents" in the claim 1 lacks antecedent basis.

b) Claim 11 recites the limitation of "a polypeptide-encoding region" in line 4. There is insufficient antecedent basis for this limitation in the claim 1. Claim 1 recites the limitations of "*a sequence of nucleotides  $E_m$  that encodes a preselected polypeptide*" and "*each  $E_m$  encodes a sequence of amino acids to which a capture agent in the collection specifically binds and the sequence of amino acids is unique in a set*". Thus the limitation of "a polypeptide-encoding region" lack antecedent basis.

c) The phrase "*polypeptide-encoding region to which a capture binds*" of claim 23 is vague and indefinite because it is unclear as to what is being capture. It is suggested that the term 'agent' is added after the term 'capture'.

d) The limitation of the "*polypeptide-encoding region to which a capture agent binds*" of claim 23, 34, and 35 is vague because it is unclear as to the metes and bound of the phrase "*polypeptide-encoding region*". As claimed in claim 1, the capture agents bind to the preselected polypeptides, which are encoded by the sequence of nucleotides  $E_m$ , (e.g. see the limitations of claim 1: "*the preselected polypeptide bind to the capture agents*" and "*a sequence of nucleotides  $E_m$  that encodes a preselected polypeptide*"). Thus it is unclear whether the phrase "*polypeptide-encoding region*" refers to the sequence of nucleotides  $E_m$  or the preselected polypeptides to which the capture agents bind.

***Claim Rejections - 35 USC § 102***

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1-9, 11-23, 25-36, 93 and 94 are rejected under 35 U.S.C. 102(b) as being anticipated by Lerner et al. (US Patent 5,573,905).

*The instant invention recites a combination. The combination comprises a) a collection of capture agents and b) a set containing a plurality of oligonucleotides.*

*Each capture agent specifically binds to a polypeptide. The collection of capture agents comprises at least M different sets of captures agents, and M is at least 10, which is the number of different sequences of amino acids encoded by the oligonucleotides for which capture agents in the collection are specific. Each set of capture agents is specific for the same sequence of amino acids, and all sets of capture agents specifically bind to different sequences of amino acids encoded by the oligonucleotides.*

*Each member of the set of oligonucleotide comprises 1) a sequence of nucleotides  $E_m$  that encodes a preselected polypeptide; 2) the preselected polypeptide bind to the capture agents; 3) the oligonucleotides are single-stranded, double-stranded, or partially double-stranded; 4) the oligonucleotide comprises the formula 5' -  $E_m$  - 3'; 5) each  $E_m$  encodes a sequence of amino acids to which a capture agent in the collection specifically binds and the sequence of amino acids is unique in a set; and 6) m is at least 10.*

Lerner et al. disclose a plurality of products (see e.g. Abstract; col. 2, lines 45-67). These products include an encoded combinatorial library, wherein each composition of the library comprises a chemical polymer and an identifier nucleotide sequences that defines the structure of the chemical polymer, and the binding reaction complexes (see e.g. col. 2, lines 45-67; col. 3, line 26-40; col. 4, line 10 thru col. 8, line 53; col. 9, lines 40-55; col. 15, lines 15-57). The composition (refers to instant claimed set of oligonucleotide) comprises the identifier nucleotide sequences, a linker molecule, and a chemical polymer (see e.g. col. 3, lines 15-20; col. 4, lines 18-27; col. 4, line 29 thru col. 8, line 53; col. 11, line 61 thru col. 13, line 12). The identifier

Art Unit: 1639

nucleotide sequences comprise a coding region (refers to instant claimed  $E_m$ ) that is flank by two different PCR (polymerase chain reaction) primers (see e.g. col. 3, lines 15-20; col. 4, lines 18-27; col. 5, line 49 thru col. 6, line 9). The primers comprises nucleotide sequences that provide polymerase chain reaction primer binding sites for amplification (refers to the instant claimed common region (variable C in the formula 5'-C- $E_m$ -3' of claim 25), and the instant claimed variable D in the formula 5'-D<sub>n</sub>- $E_m$ -3' of claim 26), and restriction sites (refers to the instant claimed divider region) such as incorporation of a biotinylated nucleotide (refers to instant claims 11-12, 15, 16, and 36) (see e.g. col. 6, line 66 thru col. 7, line 45). The length of the primer is at least 10 nucleotides (refers to instant claimed  $n=10$  of claims 26, 28-32, 94, and 95) (see e.g. ref. #P1 and P2 of fig. 2). The length of the coding region varies depending on the complexity of the library that is the chemical polymer, and in general the number of nucleotides ranges is from about 2 to about 15 (refers to instant claimed  $m=10$ , and instant claims 13, 14, 23, 24, 34, and 35) (see e.g. col. 4, lines 29-40; col. 5, lines 49-58; col. 6, lines 2-9, and lines 56-65). The chemical polymer includes polymer such as peptide polymers and the length of the polymer varies, which is typically 4 to 50 (refers to instant claimed  $M=10$ , and instant claims 17, 18, 21, 22, and 27-29) (see e.g. col. 4, lines 37-52; col. 8, line 63 thru col. 9, line 14). Additionally, the binding reaction complexes (refers to instant claimed combination) are produced by the binding interaction between the chemical polymer of the library and a biologically active molecule (refers to instant claimed capture agent) wherein the binding interaction includes interaction such as antibodies to antigen (refers to instant claims 2, 4, 33, and 93) (see e.g. col. 2, lines 61-67; col. 3, line 26-40; col. 15, lines 15-57). The biologically active molecule can be affixed to a solid support (refers to instant claims 5, and 6) (see e.g. col. 16, lines 42-67). The solid support

Art Unit: 1639

includes supports such as beads, and microtiter plate wells (refers to claims 3, 7-9, 19, and 20) (see e.g. col. 17, lines 11-21). The products of Lerner et al. anticipate the presently claimed invention.

12. Claims 1, 2, 11, 12, 25, 26, 36, 49-51, and 99 are rejected under 35 U.S.C. 102(b) as being anticipated by Dower et al. (US Patent 5,639,603).

*The instant invention recites a combination. The combination comprises a) a collection of capture agents and b) a set containing a plurality of oligonucleotides.*

*Each capture agent specifically binds to a polypeptide. The collection of capture agents comprises at least M different sets of captures agents, and M is at least 10, which is the number of different sequences of amino acids encoded by the oligonucleotides for which capture agents in the collection are specific. Each set of capture agents is specific for the same sequence of amino acids, and all sets of capture agents specifically bind to different sequences of amino acids encoded by the oligonucleotides.*

*Each member of the set of oligonucleotide comprises 1) a sequence of nucleotides  $E_m$  that encodes a preselected polypeptide; 2) the preselected polypeptide bind to the capture agents; 3) the oligonucleotides are single-stranded, double-stranded, or partially double-stranded; 4) the oligonucleotide comprises the formula 5' -  $E_m$  - 3'; 5) each  $E_m$  encodes a sequence of amino acids to which a capture agent in the collection specifically binds and the sequence of amino acids is unique in a set; and 6) m is at least 10.*

Dower et al. disclose a plurality of products (see e.g. Abstract; col. 1, lines 13-21). The products include encoded synthetic chemical libraries and the binding reaction complexes (see e.g. col. 1, lines 13-21; col. 3, line 66 to col. 4, line 18; col. 4, line 66 thru col. 5, line 11; col. 26, lines 12-42). The encoded synthetic chemical libraries (refers to instant claimed set of oligonucleotide) comprise beads, identifier tags, and oligomer (see e.g. col. 3, line 66 to col. 4, line 18; col. 9, lines 13-27; col. 23, lines 10-46; col. 26, lines 12-42; col. 44, line 61 to col. 45, line 39). The identifier tags are oligonucleotides (see e.g. col. 16, lines 15-24, and lines 48-63). Each oligonucleotide tag comprises an amplification sites (refers to the instant claimed common region/variable C), monomer specific information/coding site (refers to instant claimed  $E_m$ ), a



Art Unit: 1639

spacer segment of variable length that distant the coding site from the amplification sites (refers to instant claimed divider region), and the order-of-reaction information (refers to the instant claimed variable D) (refers to instant claims 11, 12, 25, 26, and 99) (see e.g. col. 17, lines 42-53; col. 18, line 28 thru col. 19, line 46). Each oligonucleotide tag has the length with a range of 50 to 150 nucleotides and is singled stranded oligonucleotide (refers to claim 36) (see e.g. col. 17, lines 42-53; col. 18, lines 4-9, and lines 49-63). The oligomer comprises a plurality of different peptide sequences (see e.g. col. 9, lines 13-27; col. 23, lines 10-46; col. 26, lines 12-42). The binding reaction complexes are produced by the binding interaction between the oligomers and the receptors (refers to instant claimed capture agent) such as antibodies (refers to instant claim 2) (see e.g. col. 8, lines 23-46; col. 31, lines 11-27, and lines 36-40). The binding reaction complexes were sorted by using fluorescence activated cell-sorting instrument (refers to instant claims 49-51) (see e.g. col. 26, lines 32-40; col. 31, lines 54-63; col. 45, lines 1-7). Thus the products of Dower et al. anticipate the presently claimed combination and system.

### ***Claim Rejections - 35 USC § 103***

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

Art Unit: 1639

evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

15. Claims 1-9, 11-23, 25-36, 49-51, and 93-95 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lerner et al. (US Patent 5,573,905) and Dower et al. (US Patent 5,639,603).

*The instant invention recites a combination. The combination comprises a) a collection of capture agents and b) a set containing a plurality of oligonucleotides.*

*Each capture agent specifically binds to a polypeptide. The collection of capture agents comprises at least M different sets of captures agents, and M is at least 10, which is the number of different sequences of amino acids encoded by the oligonucleotides for which capture agents in the collection are specific. Each set of capture agents is specific for the same sequence of amino acids, and all sets of capture agents specifically bind to different sequences of amino acids encoded by the oligonucleotides.*

*Each member of the set of oligonucleotide comprises 1) a sequence of nucleotides  $E_m$  that encodes a preselected polypeptide; 2) the preselected polypeptide bind to the capture agents; 3) the oligonucleotides are single-stranded, double-stranded, or partially double-stranded; 4) the oligonucleotide comprises the formula 5' -  $E_m$  - 3'; 5) each  $E_m$  encodes a sequence of amino acids to which a capture agent in the collection specifically binds and the sequence of amino acids is unique in a set; and 6) m is at least 10.*

Lerner et al. disclose a plurality of products (see e.g. Abstract; col. 2, lines 45-67). These products include an encoded combinatorial library, wherein each composition of the library comprises a chemical polymer and an identifier nucleotide sequences that defines the structure of the chemical polymer, and the binding reaction complexes (see e.g. col. 2, lines 45-67; col. 3, line 26-40; col. 4, line 10 thru col. 8, line 53; col. 9, lines 40-55; col. 15, lines 15-57). The composition (refers to instant claimed set of oligonucleotide) comprises the identifier nucleotide sequences, a linker molecule, and a chemical polymer (see e.g. col. 3, lines 15-20; col. 4, lines 18-27; col. 4, line 29 thru col. 8, line 53; col. 11, line 61 thru col. 13, line 12). The identifier

Art Unit: 1639

nucleotide sequences comprise a coding region (refers to instant claimed  $E_m$ ) that is flank by two different PCR (polymerase chain reaction) primers (see e.g. col. 3, lines 15-20; col. 4, lines 18-27; col. 5, line 49 thru col. 6, line 9). The primers comprises nucleotide sequences that provide polymerase chain reaction primer binding sites for amplification (refers to the instant claimed common region (variable C in the formula 5'-C- $E_m$ -3' of claim 25), and the instant claimed variable D in the formula 5'-D<sub>n</sub>- $E_m$ -3' of claim 26), and restriction sites (refers to the instant claimed divider region) such as incorporation of a biotinylated nucleotide (refers to instant claims 11-12, 15, 16, and 36) (see e.g. col. 6, line 66 thru col. 7, line 45). The length of the primer is at least 10 nucleotides (refers to instant claimed  $n=10$  of claims 26, 28-32, 94, and 95) (see e.g. ref. #P1 and P2 of fig. 2). The length of the coding region varies depending on the complexity of the library that is the chemical polymer, and in general the number of nucleotides ranges is from about 2 to about 15 (refers to instant claimed  $m=10$ , and instant claims 13, 14, 23, 24, 34, and 35) (see e.g. col. 4, lines 29-40; col. 5, lines 49-58; col. 6, lines 2-9, and lines 56-65). The chemical polymer includes polymer such as peptide polymers and the length of the polymer varies, which is typically 4 to 50 (refers to instant claimed  $M=10$ , and instant claims 17, 18, 21, 22, and 27-29) (see e.g. col. 4, lines 37-52; col. 8, line 63 thru col. 9, line 14). Additionally, the binding reaction complexes (refers to instant claimed combination) are produced by the binding interaction between the chemical polymer of the library and a biologically active molecule (refers to instant claimed capture agent) wherein the binding interaction includes interaction such as antibodies to antigen (refers to instant claims 2, 4, 33, and 93) (see e.g. col. 2, lines 61-67; col. 3, line 26-40; col. 15, lines 15-57). The biologically active molecule can be affixed to a solid support (refers to instant claims 5, and 6) (see e.g. col. 16, lines 42-67). The solid support

Art Unit: 1639

includes supports such as beads, and microtiter plate wells (refers to claims 3, 7-9, 19, and 20) (see e.g. col. 17, lines 11-21).

The products of Lerner et al. differ from the presently claimed invention by failing to include a computer system with software for analyzing results of sorting.

Dower et al. disclose a plurality of products (see e.g. Abstract; col. 1, lines 13-21). The products include encoded synthetic chemical libraries and the binding reaction complexes (see e.g. col. 1, lines 13-21; col. 3, line 66 to col. 4, line 18; col. 4, line 66 thru col. 5, line 11; col. 26, lines 12-42). The encoded synthetic chemical libraries (refers to instant claimed set of oligonucleotide) comprise beads, identifier tags, and oligomer (see e.g. col. 3, line 66 to col. 4, line 18; col. 9, lines 13-27; col. 23, lines 10-46; col. 26, lines 12-42; col. 44, line 61 to col. 45, line 39). The identifier tags are oligonucleotides (see e.g. col. 16, lines 15-24, and lines 48-63). Each oligonucleotide tag comprises an amplification sites (refers to the instant claimed common region/variable C), monomer specific information/coding site (refers to instant claimed  $E_m$ ), a spacer segment of variable length that distant the coding site from the amplification sites (refers to instant claimed divider region), and the order-of-reaction information (refers to the instant claimed variable D) (refers to instant claims 11, 12, 25, 26, and 99) (see e.g. col. 17, lines 42-53; col. 18, line 28 thru col. 19, line 46). Each oligonucleotide tag has the length with a range of 50 to 150 nucleotides and is singled stranded oligonucleotide (refers to claim 36) (see e.g. col. 17, lines 42-53; col. 18, lines 4-9, and lines 49-63). The oligomer comprises a plurality of different peptide sequences (see e.g. col. 9, lines 13-27; col. 23, lines 10-46; col. 26, lines 12-42). The binding reaction complexes are produced by the binding interaction between the oligomers and the receptors (refers to instant claimed capture agent) such as antibodies (refers to instant claim

Art Unit: 1639

2) (see e.g. col. 8, lines 23-46; col. 31, lines 11-27, and lines 36-40). The binding reaction complexes were sorted by using fluorescence activated cell-sorting instrument (refers to instant claims 49-51) (see e.g. col. 26, lines 32-40; col. 31, lines 54-63; col. 45, lines 1-7).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to include a computer system with software for analyzing results of sorting as taught by Dower et al. in the products of Lerner et al. One of ordinary skill in the art would have been motivated to include a computer system with software for analyzing results of sorting in the products of Lerner et al. since Lerner et al. disclose that any separation means is use to selectively isolate the binding reaction complex from binding reaction mixture (Lerner: col. 16, lines 36-41) and Dower et al. disclose that fluorescence activated cell-sorting instrument is a known in the art as a means of isolating the binding reaction complex from binding reaction mixture (Dower: col. 31, lines 50-67). Thus, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to include a computer system with software for analyzing results of sorting as taught by Dower et al. in the products of Lerner et al. Additionally, both Lerner et al. and Dower et al. disclose the assay method wherein libraries are screened for its binding ability to the receptors of interest (Lerner: col. 15, lines 27-49; Dower: col. 31, lines 28-40). Furthermore, one of ordinary skill in the art would have reasonably expectation of success in the combination of Lerner et al. and Dower et al. because Dower et al. disclose by example the success of using the fluorescence activated cell-sorting instrument for analyzing results of sorting (Dower: col. 47, lines 8-29).

Art Unit: 1639

16. Claims 1-9, 11-23, 25-36, 49-54, and 93-95 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lerner et al. (US Patent 5,573,905) and Iris et al. (US Patent 6,403,309 B1).

*The instant invention recites a combination. The combination comprises a) a collection of capture agents and b) a set containing a plurality of oligonucleotides.*

*Each capture agent specifically binds to a polypeptide. The collection of capture agents comprises at least M different sets of captures agents, and M is at least 10, which is the number of different sequences of amino acids encoded by the oligonucleotides for which capture agents in the collection are specific. Each set of capture agents is specific for the same sequence of amino acids, and all sets of capture agents specifically bind to different sequences of amino acids encoded by the oligonucleotides.*

*Each member of the set of oligonucleotide comprises 1) a sequence of nucleotides  $E_m$  that encodes a preselected polypeptide; 2) the preselected polypeptide bind to the capture agents; 3) the oligonucleotides are single-stranded, double-stranded, or partially double-stranded; 4) the oligonucleotide comprises the formula 5' -  $E_m$ -3'; 5) each  $E_m$  encodes a sequence of amino acids to which a capture agent in the collection specifically binds and the sequence of amino acids is unique in a set; and 6) m is at least 10.*

Lerner et al. disclose a plurality of products (see e.g. Abstract; col. 2, lines 45-67). These products include an encoded combinatorial library, wherein each composition of the library comprises a chemical polymer and an identifier nucleotide sequences that defines the structure of the chemical polymer, and the binding reaction complexes (see e.g. col. 2, lines 45-67; col. 3, line 26-40; col. 4, line 10 thru col. 8, line 53; col. 9, lines 40-55; col. 15, lines 15-57). The composition (refers to instant claimed set of oligonucleotide) comprises the identifier nucleotide sequences, a linker molecule, and a chemical polymer (see e.g. col. 3, lines 15-20; col. 4, lines 18-27; col. 4, line 29 thru col. 8, line 53; col. 11, line 61 thru col. 13, line 12). The identifier nucleotide sequences comprise a coding region (refers to instant claimed  $E_m$ ) that is flank by two different PCR (polymerase chain reaction) primers (see e.g. col. 3, lines 15-20; col. 4, lines 18-27; col. 5, line 49 thru col. 6, line 9). The primers comprises nucleotide sequences that provide polymerase chain reaction primer binding sites for amplification (refers to the instant claimed common region (variable C in the formula 5'-C- $E_m$ -3' of claim 25), and the instant claimed

Art Unit: 1639

variable D in the formula 5'-D<sub>n</sub>-E<sub>m</sub>-3' of claim 26), and restriction sites (refers to the instant claimed divider region) such as incorporation of a biotinylated nucleotide (refers to instant claims 11-12, 15, 16, and 36) (see e.g. col. 6, line 66 thru col. 7, line 45). The length of the primer is at least 10 nucleotides (refers to instant claimed n=10 of claims 26, 28-32, 94, and 95) (see e.g. ref. #P1 and P2 of fig. 2). The length of the coding region varies depending on the complexity of the library that is the chemical polymer, and in general the number of nucleotides ranges is from about 2 to about 15 (refers to instant claimed m=10, and instant claims 13, 14, 23, 24, 34, and 35) (see e.g. col. 4, lines 29-40; col. 5, lines 49-58; col. 6, lines 2-9, and lines 56-65). The chemical polymer includes polymer such as peptide polymers and the length of the polymer varies, which is typically 4 to 50 (refers to instant claimed M=10, and instant claims 17, 18, 21, 22, and 27-29) (see e.g. col. 4, lines 37-52; col. 8, line 63 thru col. 9, line 14). Additionally, the binding reaction complexes (refers to instant claimed combination) are produced by the binding interaction between the chemical polymer of the library and a biologically active molecule (refers to instant claimed capture agent) wherein the binding interaction includes interaction such as antibodies to antigen (refers to instant claims 2, 4, 33, and 93) (see e.g. col. 2, lines 61-67; col. 3, line 26-40; col. 15, lines 15-57). The biologically active molecule can be affixed to a solid support (refers to instant claims 5, and 6) (see e.g. col. 16, lines 42-67). The solid support includes supports such as beads, and microtiter plate wells (refers to claims 3, 7-9, 19, and 20) (see e.g. col. 17, lines 11-21).

The products of Lerner et al. differ from the presently claimed invention by failing to include a computer system with software for analyzing results of sorting.

Iris et al. discloses an array of antibody that captures oligonucleotide probes labeled with peptide tags (see e.g. Abstract; col. 1, lines 14-18; col. 2, lines 34-47). The solid phase surface comprises a plurality of loci (refers to the presently claimed addressable array), wherein each locus comprises an antibody specific to one or more of the peptides of the peptide label oligonucleotide probes (see e.g. col. 6, lines 28-31; col. 22, lines 23-29). The peptide tags are specific to the antibodies of the array (see e.g. col. 21, lines 29-39). Further, the oligonucleotide probes may be first hybridized to a target DNA before being capture by the addressable antibody arrays (see e.g. col. 15, lines 32-67 to col. 16, lines 1-11). Additionally, the array of Iris et al. comprises a computer that generates and stores the arrayed pattern of the array (refers to the presently claimed computer system and claim 53) (see e.g. col. 23, lines 18-25).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to include a computer system with software for analyzing results of sorting as taught by Iris et al. in the products of Lerner et al. One of ordinary skill in the art would have been motivated to include a computer system with software for analyzing results of sorting in the products of Lerner et al. since Lerner et al. disclose that any separation means is use to selectively isolate the binding reaction complex from binding reaction mixture wherein the receptors are bound to the solid support (Lerner: col. 16, lines 36-41, and lines 56-67) and Iris et al. disclose any method known in the art can be used for the visualization or detection of the binding reaction complex on an antibody array (Iris: col. 19, lines 27-37). Additionally, both Lerner et al. and Iris et al. disclose an array of receptors (Lerner: col. 17, lines 11-21; Iris: col. 22, line 23 thru col. 23, line 31). Furthermore, one of ordinary skill in the art would have reasonably expectation of success in the combination of Lerner et al. and Iris et al. because Iris et



Art Unit: 1639

al. disclose by example the success of fluorescent detection of binding reaction complex on an antibody array (Iris: col. 27, line 15 thru col. 30, line 10).

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to My-Chau T. Tran whose telephone number is 571-272-0810. The examiner can normally be reached on Monday: 8:00-2:30; Tuesday-Thursday: 7:30-5:00; Friday: 8:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

mct  
March 30, 2005

  
PADMASHRI PONNALURI  
PRIMARY EXAMINER